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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,646	03/20/2002	Jan Van Der Greef	101137-31	6797

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/28/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,646

Applicant(s)

GREEF ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Objections

2. Claim 11 is objected to because of the following informalities: Please insert "A" at the beginning of claim 11 for clarity. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 10 recites the limitation "orphan receptor" is vague because it is unclear as to what an orphan receptor is. Please clarify.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nedved et al (Characterization of Benzodiazepine "Combinatorial" Chemical Libraries by On-Line Immunoaffinity Extraction, Coupled Column HPLC-Ion Spray Mass Spectrometry – Tandem Mass Spectrometry, Analytical Chemistry, 1996, Vol. 68, pages 4228-4236).

Nedved et al anticipates the instant claims by teaching on-line detection methods comprising immunoaffinity extraction of analytes using reversed-phase HPLC columns coupled to a mass spectrometer (see abstract). Claim 1 is directed to adding a controlled amount of affinity molecule to an effluent followed by a separation step using a restricted-access support (see abstract). Nedved et al teaches antibodies to benzodiazepine were used to screen library components and were added to a Protein G column (effluent) wherein a pH change in the mobile phase eluted the benzodiazepine-antibody complexes on to a restricted access media column (support) thereby separating the selected benzodiazepine from the antibody (see abstract). The instant claim 1 also discloses a second step of separation whereby the analyte-affinity molecule complex is permeated flowed by a step to dissociate the analyte-affinity molecule complex followed by detection of the analyte using mass spectrometer. Nedved et al teaches a second step of backflushing the restricted access column (support) wherein

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the dissociated benzodiazepines analyte is eluted onto an analytical reversed phase column for separation and detection and characterization using mass spectrometry (see abstract and page 4229, column 2, paragraph 4). Claim 2 is directed to the use of a restricted access support in which the affinity molecule is retained followed by elution of the analyte to be detected by mass spectrometry. Nedved et al teaches a second separation step using restricted access column (support) wherein the antibody was retained after elution of the benzodiazepines analyte (page 4230, column 1 paragraph 1). Acetic acid was used to dissociate analytes with a pH of 7.4 as recited in claim 4 (page 4229, column 2, paragraphs 1-2 and page 4231 column 2, paragraph 1). The fractionation step used to separate the analytes were HPLC and other chemical combinatorial chemistry library systems as recited in claims 5 and 6 (see abstract and page 4229, column 1, paragraphs 1-2). Nedved et al discloses different instrumentation of mass spectrometer used in the detection of analytes such as MS/MS, tandem mass spectrometry and on line ion spray spectrometry as recited in claim 7 (page 4228, column 2, paragraph 2). The affinity proteins used were monoclonal and polyclonal antibodies to known benzodiazepine compositions as recited in claims 9 and 10. Known and unknown compounds such as pharmaceuticals are detected by utilizing chemical libraries as taught by Nedved et al and as recited in claim 11 (page 4228, column 2, paragraph 1).

Conclusion

8. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Blom et al teaches methods for determining ligand affinity utilizing online size exclusion chromatography and mass spectrometry (Journal of Combinatorial Chemistry, 1999, Vol. 1, pages 82-90).

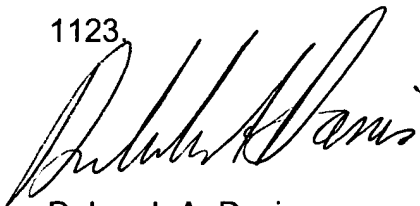
B. Haynes et al teach gel-separated protein by liquid chromatography and tandem mass spectrometry (Electrophoresis, 1998, Vol. 19, pages 939-945).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123



Deborah A. Davis
CM1, 7D16
July 19, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
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07/25/03